Remarks

Applicants respectfully request that the Amendment and Reply Under 37 C.F.R. § 1.114 filed April 30, 2008 ("Reply"), is reviewed along with the accompanying Declarations under 37 C.F.R. § 1.132 of David P. Nicolau, Pharm.D., FCCP and of Harry Bermudez, Ph.D. Based on the following remarks and submitted Declarations, as well as the remarks presented in the Amendment and Reply filed April 30, 2008, Applicants respectfully request that the Office reconsider all outstanding rejections and objections and that they be withdrawn.

As evidence of the nonobviousness of claims 16-48 and 67-73 of the current application in light of U.S. Pat. No. 7,173,102 B2 ("the '102 patent"), Applicants provide herewith as Exhibit A the Declaration under 37 C.F.R. § 1.132 of David P. Nicolau, Pharm.D., FCCP ("the Nicolau Declaration"), along with accompanying Exhibits A1 and A2 cited therein. Dr. Nicolau is an expert in the field of anti-infective agents. Dr. Nicolau was asked to evaluate the technology around the time of filing of the parent application of which the present application claims benefit.

As described in the Nicolau Declaration, Dr. Nicolau disagrees with the Examiner's conclusion that the invention encompassed by claims 16-48 and 67-73 of the current application would have been obvious to a person of ordinary skill in the art in view of the '102 patent, for at least the three following reasons.

First, as disclosed in the Nicolau Declaration, Dr. Nicolau is of the opinion that "a person of ordinary skill in the art would not necessarily expect the polymers described in the '102 patent to be effective when administered to an animal with a microbial infection." (The Nicolau Declaration, pp. 3-4, ¶8.) According to Dr. Nicolau, "the '102

patent is silent with respect to the route by which one of the disclosed polymers would be administered to an animal." *Id.* Moreover, Dr. Nicolau notes "[t]he '102 patent does not describe any carriers or diluents which are compatible with the polymers and which may be used to formulate a pharmaceutical composition." *Id.* Accordingly, it is Dr. Nicolau's opinion that "a person of ordinary skill in the art would not necessarily expect a polymer shown to function as an antimicrobial agent when attached to or incorporated into an object to be effective in treating a microbial infection in an animal." *Id.*

Second, as described in the Nicolau Declaration, Dr. Nicolau is of the opinion that, "a person of ordinary skill in the art would not necessarily expect the polymers described in the '102 patent to be effective when administered to an animal with a microbial infection simply because an *in vitro* assay showed the polymers inhibit bacterial growth." (*Id.* at pp. 4-5, ¶9.) Dr. Nicolau notes that "a person of ordinary skill in the art is aware that the *in vitro* assays disclosed in the '102 patent do not necessarily indicate whether the compound would be effective *in vivo*." *Id.* Therefore, it is Dr. Nicolau's opinion that "a person of ordinary skill in the art would not necessarily expect a polymer shown to have antimicrobial activity *in vitro* to be effective to treat an animal with a microbial infection when administered as a pharmaceutical composition." *Id.*

Finally, as set forth in the Nicolau Declaration, Dr. Nicolau is of the opinion that, "a person of ordinary skill in the art would not necessarily expect the polymers described in the '102 patent to be effective when administered to an animal with a microbial infection simply because the polymers were tested for toxicity to birds, fish and mammals." (*Id.* at p. 5, ¶10.) In particular, the Nicolau Declaration states that "[a] person of ordinary skill in the art would read the disclosure in the '102 patent regarding the reduced toxicity of the polymers to birds, fish and mammals as being related to

toxicity studies, such as those required by the U.S. Environmental Protection Agency ("EPA")." *Id.* Thus, it is Dr. Nicolau's opinion that "a person of ordinary skill in the art would not necessarily expect that a polymer to be used as an additive or applied to the surface of an object and having acceptable toxicity to necessarily be safe when administered to an animal." *Id.*

In summary, it is Dr. Nicolau's opinion that "a person of ordinary skill in the art, based upon the disclosures of the '102 patent, would not have been motivated to treat a microbial infection in an animal by administering an effective amount of a pharmaceutical composition containing an oligomer of a specific structure and a pharmaceutically acceptable carrier or diluent, as claimed in the patent application." (*Id.*, at p. 6, ¶ 11.)

As further evidence of the nonobviousness of claims 16-48 and 67-73 of the current application in light of the '102 patent, Applicants provide herewith as Exhibit B, the Declaration under 37 C.F.R. § 1.132 of Harry Bermudez, Ph.D. along with accompanying Exhibit B1 cited therein ("the Bermudez Declaration"). Dr. Bermudez has expertise in the field of biopolymers. Dr. Bermudez was asked to evaluate the technology around the time of filing of the parent application of which the present application claims benefit.

As described in the Bermudez Declaration, Dr. Bermudez disagrees with the Examiner's conclusion that a person of ordinary skill in the art would have been motivated to treat an animal with a microbial infection by administering a pharmaceutical composition containing an amphiphilic oligomer of Formula II with 1 to about 20 monomer units and a pharmaceutically acceptable carrier or diluent, in light of the '102 patent for at least the three following reasons.

First, as described in the Bermudez Declaration, it is Dr. Bermudez's opinion that "the '102 patent indicates that the disclosed polymers can be applied to, or dispersed throughout, an object and does not describe a method of treating a microbial infection in an animal." (The Bermudez Declaration, p. 3, ¶7.) Dr. Bermudez opines "[t]here is no disclosure in the '102 patent suggesting that the disclosed polymers could be used other than for surface applications." *Id.* Dr. Bermudez further opines that the '102 patent provides no guidance (1) "as to how to formulate the polymers with a carrier or diluent" or (2) "by what route the polymers may be administered, such as parenteral, oral, or transdermal administration." *Id.* Based on the above, it is Dr. Bermudez's opinion that "a person of ordinary skill in the art would not expect that a polymer to be applied to the surface of, or incorporated into, an object would necessarily be effective when administered to an animal to treat a microbial infection." *Id.*

Second, it is Dr. Bermudez's opinion that "a person of ordinary skill in the art would not expect that an oligomer containing only 1 to about 20 monomer units to be applied to the surface of an object would necessarily be effective when administered to an animal to treat a microbial infection." (*Id.* at pp. 3-4, ¶8.) Dr. Bermudez notes that "the '102 patent discloses the polymers applied to the surface of an object are more prone to leach from the object if the polymers have a molecular weight of about 0.8 kD to about 20 kD." *Id.* Dr. Bermudez indicates that "a person of ordinary skill in the art, when applying the polymers disclosed in the '102 patent to the surface of an object, would be motivated to use a polymer having a number of monomer units at the higher end of the disclosed range." *Id.* Accordingly, it is Dr. Bermudez's opinion that "a person of ordinary skill in the art would not have been motivated to treat an animal with a microbial infection by administering a pharmaceutical composition containing an

amphiphilic oligomer of Formula II with 1 to about 20 monomer units and a pharmaceutically acceptable carrier or diluent, as claimed in the [above-captioned] patent application, in view of the '102 patent." *Id.*

Finally, as set forth in the Bermudez Declaration, Dr. Bermudez is of the opinion that "a person of ordinary skill in the art would not conclude from [the] disclosure in the '102 patent the polymers would not be toxic and would be safe to be administered as a pharmaceutical composition to treat a mammal with a microbial infection." (*Id.* at pp. 4-5, ¶9.) The Bermudez Declaration states that "[a] person of ordinary skill in the art would not assume from that a single *in vitro* experiment that the polymers described in the '102 patent are safe and effective and may be administered to an animal." *Id.* In fact, Dr. Bermudez notes "a person of ordinary skill in the art would be concerned that a metabolite formed from the degradation of the polymer after administration may be toxic." *Id.* Dr. Bermudez further notes, "[t]he '102 patent provides no information regarding the toxicity of any metabolites." *Id.* Therefore, it is Dr. Bermudez's opinion that "a person of ordinary skill in the art would not have been motivated to treat an animal with a microbial infection by administering a pharmaceutical composition containing an amphiphilic oligomer of Formula II and a pharmaceutically acceptable carrier or diluent, as claimed in the [above-captioned] patent application, in view of the '102 patent." *Id.*

In summary, Dr. Bermudez is of the opinion that "a person of ordinary skill in the art would not have been motivated to treat an animal with a microbial infection by administering a pharmaceutical composition containing an amphiphilic oligomer of Formula II with 1 to about 20 monomer units and a pharmaceutically acceptable carrier

or diluent, as claimed in the [above-captioned] patent application, in view of the '102 patent." (*Id.* at pp. 5-6, ¶ 10.)

Based on the foregoing, Applicants respectfully request that all outstanding rejections and objections be withdrawn.

Conclusion

All of the stated grounds of rejection and objection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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